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Health Information Exchange (HIE) Advisory Commission
September 10, 2015
Meeting Minutes (DRAFT)

Attendance:
Commission Members: David Gorelick, MD (Chair); Lisa Shea, MD; Ted Almon
State Staff: Melissa Lauer (RIDOH); Amy Zimmerman (EOHHS); Nicole Alexander-Scott, MD, MPH (Director of Health), John Fulton (RIDOH), Jane Morgan (RIDOH)
Guests: Amy Nunn, ScD (Rhode Island Public Health Institute), Elaine Fontaine (Rhode Island Quality Institute), Mike Dwyer (Rhode Island Quality Institute), Alok Gupta (Rhode Island Quality Institute), Lauren Morton (Blue Cross Blue Shield of Rhode Island)

1) **Meeting Called to Order:** at 3:30PM by Chair, Dr. David Gorelick.
   a) Introductions
   b) A motion was made by Mr. Almon to approve the minutes and seconded by Dr. Shea. The minutes (August 6, 2015) were approved unanimously.

2) **Public Comment:**
   a) None

3) **HIE Data Release for Public Health Functions**
   a) Developing Data Release Criteria
      - Must determine if HIE is considered a Department of Health (DOH) data set, because then it has to be reviewed by DOH Institutional Review Board (IRB). Ms. Lauer will get a definite answer to this question by the next meeting. There is some question
      - Ms. Lauer went over the basics of an IRB.
        - In any scenario where a data request includes health data on a line item level for a patient, and IRB must review the use of the data to ensure appropriate and safe involvement of human subjects in research.
        - Exempt data requests are anything that is clearly not research. Sometimes this includes external requests that are not necessarily research, but research-like. A lot of DOH work is surveillance rather than research and therefore would be exempt from IRB review.
        - It is recommended by the RIDOH IRB Chair, that all requests that are unclear go to the IRB for final determination of whether the request is exempt. IRB should make decision on anything that looks like individual level data, because the IRB decides whether it is exempt.
        - Aggregated data requests are not subject to the IRB review.
      - Additional IRB Notes:
        - Dr. Fulton recommend to have a defined rule for release of small number data. For example: some cells in delivered report could have numbers,

and others that would have too small of numbers could have redacted cells marked with N/A.
    - Decedents are not human subjects, but if they used decedents to get to someone else like relatives or a physician, it becomes human subject.
    - If risk to human subjects is extremely low, the request could be exempt.
    - Public health function Dr. Fulton – defining that – research outside of DOH. Zimmerman – could be operating in partnership with DOH to complete a function of DOH.
    - IF researcher gets clear from their IRB, then they need IRB approval from owner of the data. Need an IRB themselves or a formal relationship with another IRB to approve that the outside IRB will be their IRB. RIDOH IRB has that kind of agreement for particular kinds of review so the CDC can be the DOH IRB for some things.
    - Dr. Fulton clarifies the IRB is a parallel process to the data request.
    - Dr. Fulton adds that if data are released and there is a complaint, should it be determined that no IRB reviewed the data release, the data steward could lose federal funding.
- Discussion regarding the IRB for HIE data release requests:
    - Dr. Fulton – if HIE uses federal funds then release of data probably needs to be reviewed by an IRB because it needs to weigh in on whether a use of data is exempt from the regulations or not.
    - Dr. Shea points out it may be nice to have data requests go to the HIE Advisory Commission first to see if the data use is for a public health function before they are sent to the IRB. This would eliminate the use of the IRB in cases where the HIE data could not be legally released.
    - Dr. Alexander-Scott suggests that HIE Advisory Commission could receive a letter of intent to request data before the request goes through the IRB process so that the request can be reviewed for whether it meets the public health function criteria.
    - Dr. Fulton explains – any time if Dr. Alexander-Scott feels that DOH should delegate to another IRB she can choose to do that. The legal relationship could be arranged for a particular type of review. This would come into play if it were determined the alternative IRB has a greater understanding for clinical data, for example.
- The commission discussed potential criteria:
    - IRB: Any requests subject to IRB must go through an IRB. Dr. Alexander-Scott says that entities requesting data are used to having to meet multiple requirements.
    - Public health function: Dr. Alexander-Scott gives an example of public health practice – a report / white paper on before and after an intervention with public health entity.
    - Data security – the commission members ask if someone else in DOH could analyze data security, since none of the members have expertise in this subject matter.
        - Dr. Gorelick suggests that an IRB process would include a data management and security portion. Any request that goes through an IRB should have a thorough data security review; however, Ms. Morgan states that while data security may be considered by the

IRB, data security is not always included in IRB decision document.
        - A data use agreement will include statements attesting to the data's security.
    - Mr. Almon states that while he thinks the HIE Advisory Commission and RIDOH should be cautious about data release, there are some great uses for the data.

b) Data Release Recommendations
    - No formal recommendations have been made.

4) Schedule and Topics for Future Meetings

- The October 1 meeting date is being rescheduled for October 22, 2015 from 3:30PM to 5:00PM. The topic will be to continue to discuss the data release process.
- Members discussed the possibility of creating a short meeting for approving the final recommendation after the October 22, 2015.

5) Meeting Adjourned at 5:00 PM